Point-of-Care Testing for STIs:
Barriers and Opportunities from Test Development to Adoption

NASEM Committee on Prevention and Control of STIs in the US

October 7, 2019
What is a Point-of-Care Test?

Family Practice

- “A test to support clinical decision making performed by a qualified member of the practice staff nearby the patient…”

- “…during or very close to the time of consultation”

- “…to help the patient and physician to decide upon the best suited approach”

- “…the results should be known at the time of clinical decision making.”

STI testing: broader range of users, settings and methods for delivering test results


Point-of-Care Testing: The Potential

What can POC STI testing do?

• Empower health care providers to make informed decisions during patient visit
  ➢ Increase diagnostic capacity
  ➢ Guide delivery of timely and appropriate treatments

• Improve health care access in remote areas or areas with provider shortages

• Facilitate patient self-testing

• Enable new or growing models of delivering care (e.g., pharmacist-based testing, home health, telehealth, retail clinics)
Point-of-Care Testing: The Challenges

What is the reality of POC testing?

• Poor understanding of clinical needs and end-user perceptions
• Limited evidence of impact of testing on patient outcomes
• Lack of awareness of test availability or test value by providers
• Concerns about costs and reimbursement
• Concerns about changes needed to effectively implement and manage POC testing programs
• Concerns about impact on workload/workflow
• Need for improvements in quality assurance and user training
• Need for data connectivity

Challenges with adoption/implementation are limiting the potential impact of POC testing!
## Device Development Approaches

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<th>Value-Based</th>
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<td><strong>Characteristics</strong></td>
<td><strong>Limitations/Barriers</strong></td>
<td><strong>Decision Factors for Investment in Development (developer/funder)</strong></td>
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<tr>
<td>Motivated by desire to push technological capabilities</td>
<td>Motivated by desire to solve clinical problem</td>
<td>Motivated by desire to achieve outcomes (clinical, process, economic) and benefits for all stakeholders</td>
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<tr>
<td>No clinical focus but shared understanding of key challenges: multiplexing, signal detection, sample preparation, device integration, miniaturization, cost</td>
<td>Needs reflect clinical or “user” perceptions</td>
<td>Goes beyond clinical perceptions to consider system-level needs and broad stakeholder perspectives</td>
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<tr>
<td>Limited use of biological samples</td>
<td>Process can result in identification of technical specifications</td>
<td>Context is important</td>
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<td>No clear performance targets</td>
<td>“Expressed” clinical needs might not capture all aspects of problem</td>
<td>Definitions of value vary</td>
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<tr>
<td>Long time horizon for applying advances toward clinical application</td>
<td>Needs assessments assume test is best solution to clinical problem</td>
<td>Working within specific contexts in resource-intensive</td>
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<td>Career factors can prevent sustained attempt to solve difficult problems</td>
<td>Pressure to demonstrate outcomes; clinical performance isn’t enough</td>
<td>Value concepts and methodologies are new and evolving</td>
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<td>Novelty</td>
<td>Guiding implementation also important</td>
<td>Evidence can be difficult or costly to obtain to support value propositions</td>
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<td>Potential to impact a range of applications</td>
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<tr>
<td>Diversification of technology portfolio</td>
<td>Detailed definition of clinical needs and technical specifications</td>
<td>Recognized value drivers for proposed test within care pathway</td>
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<td>Potential to leverage developments from another field</td>
<td>Appropriate partnerships to ensure access to clinical samples/study design expertise</td>
<td>Adopter decision processes that allow value to be demonstrated</td>
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<tr>
<td></td>
<td>“Match” between enabling technology and performance rqmts</td>
<td>Clear approach to develop evidence that is needed to demonstrate value</td>
</tr>
</tbody>
</table>
Clinical Needs-Driven

Decision Factors for Investment in Development

- Detailed definition of clinical needs and technical specifications
- Appropriate partnerships to ensure access to clinical samples/study design expertise
- "Match" between enabling technology and specifications
- Ability to use technology platform for other clinical applications

Improving Information Resources for Developers

Produce and disseminate detailed performance requirements for a range of clinical needs related to STI testing; verify unmet needs in high-impact contexts of use; create tools to evaluate devices at early stages of development relative to needs

Create more opportunities for collaboration with STI researchers

Create resources to inform developers about changes to evidence requirements and appropriate study design

The regulatory landscape is changing!

**FDA**: Focus on advancing innovations; making clinical trials more efficient; producing more product-specific guidance; using real-world evidence

**EU**: (MDR/IVDR) Stricter evidence and post-market surveillance requirements; challenges with implementing changes could negatively impact innovation and test availability in the near term

**IMDRF**: Accelerating international medical device regulatory harmonization
Decision Factors for Investment in Development

- Recognized value drivers for high impact contexts
- Adopter decision processes that allow value to be demonstrated
- Pathway to develop evidence needed to demonstrate value

Identify and communicate value drivers for POC STI testing that capture the perspectives of all stakeholders

Develop value frameworks and structured decision processes to support value-based adoption decisions for introducing POC STI tests

Develop tools to assess likelihood of implementation success and guide implementation of POC STI testing in high-impact settings

What is the Value Proposition for POC STI Testing?
Creating Value Propositions

- Providing guidance on evidence needed to demonstrate value of STI tests
- Working on coverage, reimbursement, and policy challenges
- Understanding and guiding adoption decisions within provider organizations
- Developing tools to assist with implementation planning
- Developing metrics and tools to evaluate implementation success

Evaluating Value Propositions

- Working on coverage, reimbursement, and policy challenges
- Understanding and guiding adoption decisions within provider organizations
- Developing metrics and tools to evaluate implementation success

Role of public health/health services researchers?
Defining Value for Technology Adoption

**Value-Based Procurement**

**Diagnostics**

The value proposition for point-of-care testing in healthcare: HbA1c for monitoring in diabetes management as an exemplar

Christopher P. Price & Andrew St John


**A Framework for Comprehensive Assessment of the Value of Diagnostic Tests**

May 2017

https://www.advamed.org/issues/payment-health-policy/value-initiative

**ISPOR Task Force Report**


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Spanning the Development/Adoption Gap

The MaRS EXCITE Program (Ontario)

Excellence in Clinical Innovation and Technology Evaluation

The MaRS EXCITE program:

• provides developers with an early indication of fit with healthcare system
• supports developers in understanding evidence needed to meet key stakeholder requirements with a focus on a single, harmonized evidence generation (regulatory/reimbursement)
• has a process that includes “conditions of adoption” analysis:
  • identifying relevant systemic barriers to adoption
  • supporting system changes necessary for implementation

EXCITE International: not-for-profit global collaboration of key stakeholders — innovators/industry, regulators, payers, health systems, patients, scientists and end-users — working together in the premarket space to change the paradigm of health technology innovation and adoption.

https://www.marsdd.com/service/mars-excite/   http://www.exciteinternational.com/site/about
Thank You!

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